

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: )  
)  
Thomas Zdeblick et al. )  
)  
Patent No. 5,782,919 )  
)  
Issued: July 21, 1998 )  
)  
INTERBODY FUSION DEVICE ) August 30, 2002  
AND METHOD FOR RESTORATION )  
OF NORMAL SPINAL ANATOMY )

**APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156**

Assistant Commissioner of Patents  
BOX PATENT EXT.  
Washington, DC 20231

Sir:

Pursuant to the provisions of 35 U.S.C. § 156, and in compliance with 37 C.F.R. 1.710 et seq., SDGI Holdings, Inc. (SDGI), a corporation of the state of Delaware with a principal place of business located at 1800 Pyramid Place, Memphis, Tennessee 38132, a subsidiary of Medtronic Sofamor Danek, Inc. (MSD), and the owner of the above-identified patent, by its undersigned agent hereby makes application for an extension of the patent term of its U.S. Patent No. 5,782,919, from July 21, 2015 to July 2, 2016, in accordance with the following.

(1) The approved product that is the subject of this application is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act (FDCA) and is indicated for spinal fusion procedures in treating degenerative disc disease, comprising the following unit: the InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device (hereinafter the "Device").

(2) The regulatory review of the approved product was conducted by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) under Sections 515 and 520 of the FDCA.

(3) By letter dated July 2, 2002, the Office of Device Evaluation of the CDRH granted permission to begin commercial distribution of the approved product.

(4) This Application is being submitted within the sixty-day period permitted for submission of such application for extension of patent terms pursuant to 35 U.S.C. §156(d)(1) and 37 C.F.R. § 1.720(f), the last day of said sixty-day period being August 31, 2002. Because August 31, 2002 falls on a Saturday, and Monday, September 2, 2002 is a Federal holiday (Labor Day), the last day upon which this Application could be timely submitted is Tuesday, September 3, 2002.

(5) United States Patent No. 5,782,919, entitled Interbody Fusion Device And Method For Restoration Of Normal Spinal Anatomy, is the patent for which a term extension is being sought. Application Serial No. 08/411,017 was filed on March 27, 1995, and did not claim priority to any prior application. Application Serial No. 08/411,017 issued as U.S. Patent No. 5,782,919 on July 21, 1998 in the name of Thomas Zdeblick, Eddie Ray, III, and Lawrence M. Boyd, with SDGI Holdings, Inc. as Assignee. Pursuant to 35 U.S.C. § 154(a)(2), the expiration date of U.S. Patent No. 5,782,919 is the later of twenty years from the filing date or seventeen years from the issue date, or July 21, 2015.

(6) A copy of U.S. Patent No. 5,782,919, including the entire specification (including claims) and drawings, is appended hereto.

(7) A copy of the receipt for the 3½ year maintenance fee remitted for U.S. Patent No. 5,782,919 is appended hereto. A copy of the terminal disclaimer filed in connection with

U.S. Patent No. 5,782,919 is also appended hereto. There are no other receipts of maintenance fee payments, disclaimers, certificates of correction, or re-examination certificates that have issued to date with respect to U.S. Patent No. 5,782,919.

(8) United States Patent No. 5,782,919 claims the approved product identified in paragraph (1) above, and following is a showing which lists each applicable claim of said Patent and demonstrates the manner in which at least one such patent claim of said Patent reads on the approved product.

The Device features an intervertebral fusion device comprising a spacer component for carrying bone growth promoting material, as claimed in claims 1-10 and 12-14 of the Patent. It is indicated for treatment of a spinal condition known as degenerative disc disease by promoting fusion between two adjacent vertebrae. The following demonstrates the manner in which those claims read on the approved product or on a method for manufacturing or using the approved product:

Claim 1 reads on the approved product as follows. The Device is a fusion device for facilitating arthrodesis in the disc space between adjacent vertebrae, as the preamble of claim 1 states. It includes an elongated body having two ends and a length between those ends. The first end has a diameter greater than the space between the adjacent vertebrae. The body defines a hollow interior that is sized to receive bone growth promoting material (e.g. an absorbable sponge and the bone morphogenetic protein (BMP) known as rhBMP-2). The body has an outer surface with a pair of opposite cylindrical portions that (1) extend along substantially the entire length of the body and (2) define the diameter at the first end. Two substantially flat opposite side walls are connected between the cylindrical portion and extend along a substantial portion of

said length of the body. External threads are defined on the cylindrical portions and extend along substantially the entire length of the body.

(9) The relevant dates and information pertinent to 35 U.S.C § 156(g) and 37 C.F.R. (a)(10)(v), which are being provided in order to enable the Secretary of Health and Human Services to determine the applicable “regulatory review period,” follow:

Effective date of Investigational Device Exemption (IDE) #G960065	November 20, 1996
First clinical implant under IDE #G960065	January 9, 1997
Application for product approval initially submitted under PMA #P000058	January 12, 2001
PMA #P000058 approved	July 2, 2002

(10) A brief description of the activities undertaken during the applicable “regulatory review period” with respect to the approved product, and the significant dates applicable to such activities, follow:

October 22, 1996	Filed application for an Investigational Device Exemption (IDE)
November 20, 1996	FDA conditionally approved application for IDE, #G960065
December 18, 1996	Pilot Study (14 patients) received FDA approval
January 9, 1997	First surgery with device in Pilot Study
February 10, 1997	FDA unconditionally approved application for IDE, #G960065
April 7, 1997	Last surgery with device in Pilot Study
August 28, 1997	Clinical report on Pilot Study submitted to FDA
May 21, 1998	12-month report on Pilot Study and request for Pivotal trial submitted to FDA
June 19, 1998	Open Study conditionally approved by FDA with deficiencies
July 1, 1998	Response to deficiencies for Open Study submitted to FDA
July 31, 1998	Open Study received FDA approval
August 12, 1998	Proposal for Laparoscopic Study submitted to FDA
August 25, 1998	First surgery with device in Open Study
September 11, 1998	Laparoscopic Study received conditional FDA approval
November 5, 1998	First surgery with device in Laparoscopic Study
December 22, 1998	Laparoscopic Study received unconditional FDA approval
July 1, 1999	Last surgery with device in Open Study (279 total patients)
August 25, 1999	Last surgery with device in Laparoscopic Study (134 total patients)
September 28, 1999	Final report submitted for Pilot Study

December 17, 1999	Annual report submitted for open and laparoscopic Pivotal studies
April 4, 2000	Preclinical PMA module (first of three modules) submitted to FDA
August 3, 2000	FDA deficiency letter for Module 1 received
September 21, 2000	Response to FDA deficiency letter for Module 1 submitted
December 21, 2000	Clinical PMA module (second of three modules) submitted to FDA
January 12, 2001	Manufacturing PMA module (third of three modules) received by FDA
March 19, 2001	Amendment to PMA application received by FDA
March 27, 2001	FDA issues "suitability for filing" letter and grants expedited review
May 9, 2001	Amendment to PMA application received by FDA
May 31, 2001	FDA inspection of Warsaw, Indiana manufacturing facility
June 5-12, 2001	FDA inspection of Memphis clinical facilities
July 9, 2001	Deficiency letter received from FDA
July 31, 2001	Amendment to PMA application received by FDA
August 24, 2001	MSD's response to FDA's deficiency letter received by FDA
September 25, 2001	Amendment to PMA application received by FDA
October 9, 2001	Amendment to PMA application received by FDA
November 21, 2001	Amendment to PMA application received by FDA
December 6, 2001	Amendment to PMA application received by FDA
December 7, 2001	Amendment to PMA application submitted to FDA
December 26, 2001	Amendment to PMA application received by FDA
January 10, 2002	Meeting of FDA/CDRH review panel, resulting in unanimous approval recommendation

January 22, 2002	Amendment to PMA application received by FDA
February 8, 2002	Amendment to PMA application received by FDA
February 20, 2002	“Approvable” letter received from FDA
February 11-15, 2002	FDA inspection of Abbott Laboratories
March 19, 2002	Amendment to PMA application submitted to FDA
April 1-8, 2002	FDA inspection of Genetics Institute
April 2, 3, 12, 15 16, 17, 22, 26, 30, 2002	Amendments to PMA application submitted to FDA
May 7-9, 2002	FDA inspection of MSD’s Memphis Operations facilities
May 9, 10, 14, 28, 2002	Amendments to PMA application submitted to FDA
June 3-6, 2002	FDA inspection of Memphis Clinical facilities
June 12 and 28, 2002	Amendments to PMA application submitted to FDA
July 2, 2002	Date of FDA’s PMA approval letter



(11) In the opinion of SDGI, U.S. Patent No. 5,782,919 is eligible for an extension of its term as herein requested, and a statement as to the length of the term extension requested, including how the length of the extension was determined, follows:

An extension of the term of U.S. Patent No. 5,782,919 of 347 days from July 21, 2015 to and including July 2, 2016 is being requested.

As noted in paragraph 5 above, the current expiration date of U.S. Patent No. 5,782,919 is July 21, 2015, which is 17 years from its issue date.

Pursuant to 35 U.S.C. § 156(c), the term of a patent eligible for extension under § 156(a) shall be extended by the time equal to the “regulatory review period” (as defined in § 156(g)) for the approved product that occurred after the patent issued. Section 156(c) sets forth four exceptions: (1) the eligible period is reduced by any period during which the applicant did not act with due diligence (there is no such period believed to be pertinent herein); (2) after deductions, if any, under (1), the remaining period calculated under § 156(g)(3)(B)(i) (for approved products that are medical devices) is reduced by one-half; (3) the sum total of the remaining original term of the patent after product approval and the “regulatory review period” (as defined in § 156(g)) may not exceed fourteen years; and (4) only one patent may be extended for a given regulatory review period.

The applicable “regulatory review period” herein is calculated under § 156(g)(3)(A) and (B), by taking one-half of the period calculated under § 156(g)(3)(B)(i) and adding thereto the period calculated under § 156(g)(3)(B)(ii), as follows (see paragraphs 9 and 10 above):

Date clinical investigations on humans  
involving the device was begun

November 20, 1996

Date an application was initially submitted with respect to the device under FDCA section 515	January 12, 2001
Intervening period (i) [§ 156(g)(3)(B)(i)]	1514 days
One-half of intervening period (i)	757 days
Date an application was initially submitted with respect to the device under FDCA section 515	January 12, 2001
Date such application was approved	July 2, 2002
Intervening period (ii) [§ 156(g)(3)(B)(ii)]	536 days

The maximum “regulatory review period” to which SDGI is entitled under § 156(c) is believed to be the sum of one-half of intervening period (i) plus the full intervening period (ii), or 757 days + 536 days = 1293 days. The full amount of this extension would extend past the date fourteen (14) years from the date of approval (i.e. July 2, 2016), and therefore SDGI believes it is entitled to an extension of the term of U.S. Patent No. 5,782,919 of 347 days, to and including July 2, 2016.

(12) SDGI acknowledges its duty to disclose to the United States Patent and Trademark Office and the Secretary of Health and Human Services any information that is material to the determination of entitlement to the extension sought in the instant application for extension of patent term.

(13) The prescribed fee of \$1120.00 for receiving and acting upon the instant application for extension of patent term is enclosed herewith. Please charge any underpayment or additional fee that may be due to Deposit Account 23-3030.

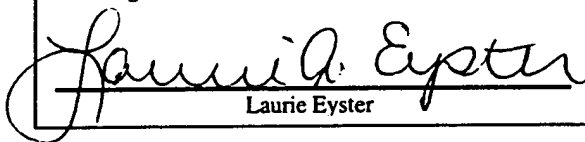
(14) The name, address, and telephone number of the person to whom inquiries should be made and correspondence relating to this application are to be directed is: Christopher A.



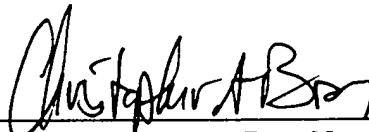
Brown, Esq., Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, 111 Monument Circle, Suite 3700, Indianapolis, Indiana 46204-5137, (317) 634-3456.

"Express Mail" label number EV 120987501US  
Date of Deposit August 30, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

  
Laurie Eyster

Respectfully submitted,



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4002-209:CAB:180149



US005782919A

# United States Patent [19]

Zdeblick et al.

[11] Patent Number: 5,782,919  
[45] Date of Patent: \*Jul. 21, 1998

## [54] INTERBODY FUSION DEVICE AND METHOD FOR RESTORATION OF NORMAL SPINAL ANATOMY

[75] Inventors: Thomas Zdeblick, Madison, Wis.;  
Eddie Ray, III, Cordova; Lawrence M. Boyd, Memphis, both of Tenn.

[73] Assignee: SDGI Holdings, Inc., Memphis, Tenn.

[\*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,669,909.

[21] Appl. No.: 411,017

[22] Filed: Mar. 27, 1995

[51] Int. Cl.<sup>6</sup> ..... A61F 2/44

[52] U.S. Cl. .... 623/17; 606/61

[58] Field of Search ..... 623/16, 17, 18;  
606/61

## [56] References Cited

### U.S. PATENT DOCUMENTS

3,848,601	11/1974	Ma et al.	128/305
4,349,921	9/1982	Kuntz	3/1
4,501,269	2/1985	Bagby	
4,714,469	12/1987	Kenna	623/17
4,743,256	5/1988	Brantigan	623/18
4,834,757	5/1989	Brantigan	623/17
4,878,915	11/1989	Brantigan	623/17
4,936,848	6/1990	Bagby	623/17
4,961,740	10/1990	Ray et al.	606/61
5,015,247	5/1991	Michelson	623/17
5,055,104	10/1991	Ray	606/61
5,192,327	3/1993	Brantigan	623/17
5,282,861	2/1994	Kaplan	623/16
5,458,638	10/1995	Kuslich et al.	623/17
5,609,636	3/1997	Kohrs et al.	623/17

## OTHER PUBLICATIONS

U.S. application No. 08/480,908. Michelson, Filed Jun. 7, 1995.

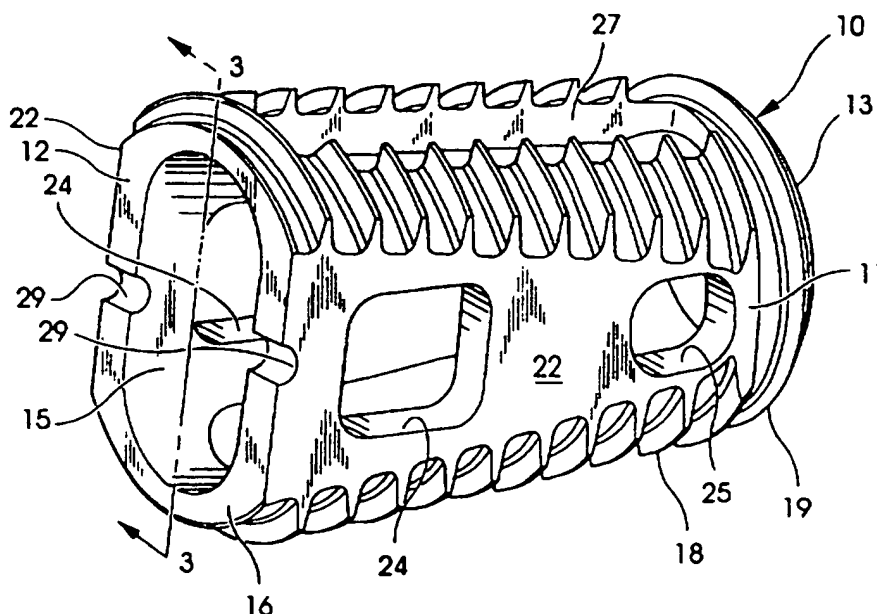
Primary Examiner—David Isabella

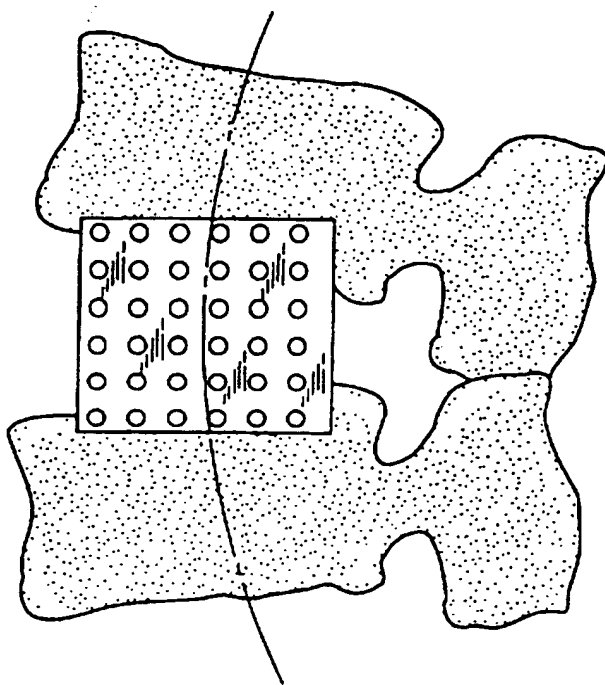
Attorney, Agent, or Firm—Woodard, Emhardt, Naughton, Moriarty & McNett

## [57] ABSTRACT

An interbody fusion device includes a tapered body defining a hollow interior for receiving bone graft or bone substitute material. The body defines exterior threads which are interrupted over portions of the outer surface of the device. The fusion device defines truncated side walls so that on end view the body takes on a cylindrical form. The side walls are provided with vascularization openings, and the body wall device includes opposite bone ingrowth slots extending through the interrupted thread portion of the body. An implant driver is provided which engages the truncated side walls to complete the cylindrical form of the implant at the root diameter of the interrupted threads. The driver facilitates threaded insertion of the implant to the intra-discal space between adjacent vertebrae. The implant is tapered at a predetermined angle generally corresponding to a desired lordotic angle of the spine. The implant is inserted to a determinant depth into the intra-discal space to restore the normal lordosis of the particular vertebral level. The lordotic angle is restored not only by way of the taper of the implant itself, but also as a function of the depth of insertion of the implant into the space. The implant is readily adapted for insertion from either an anterior or a posterior approach. In the anterior approach, the implant is screw threaded into position, while in the posterior approach the implant operates as a cam to spread the vertebral bodies apart to an appropriate lordotic angle.

14 Claims, 10 Drawing Sheets





*Fig. 1*  
(PRIOR ART)

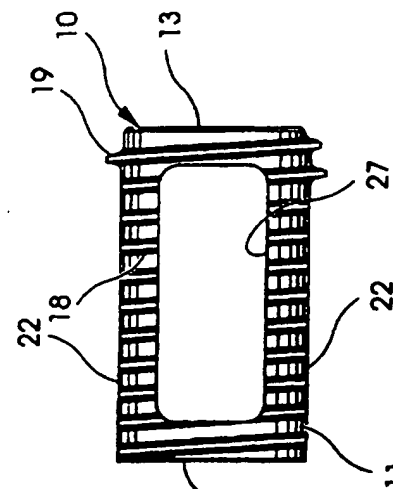


Fig. 5

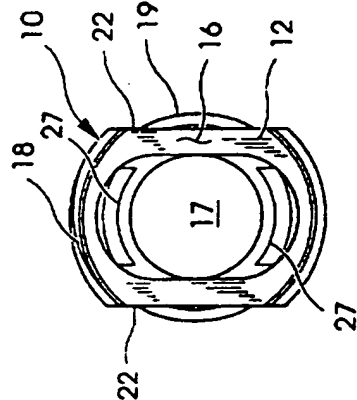


Fig. 4

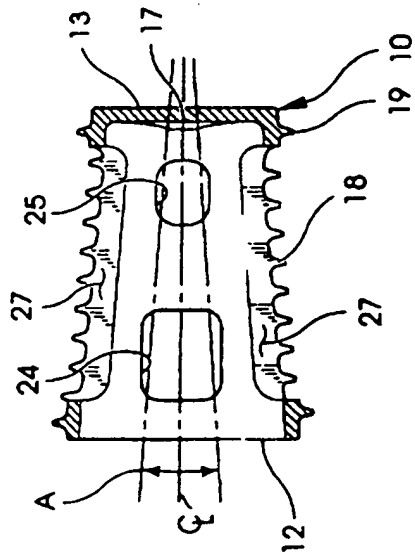


Fig. 3

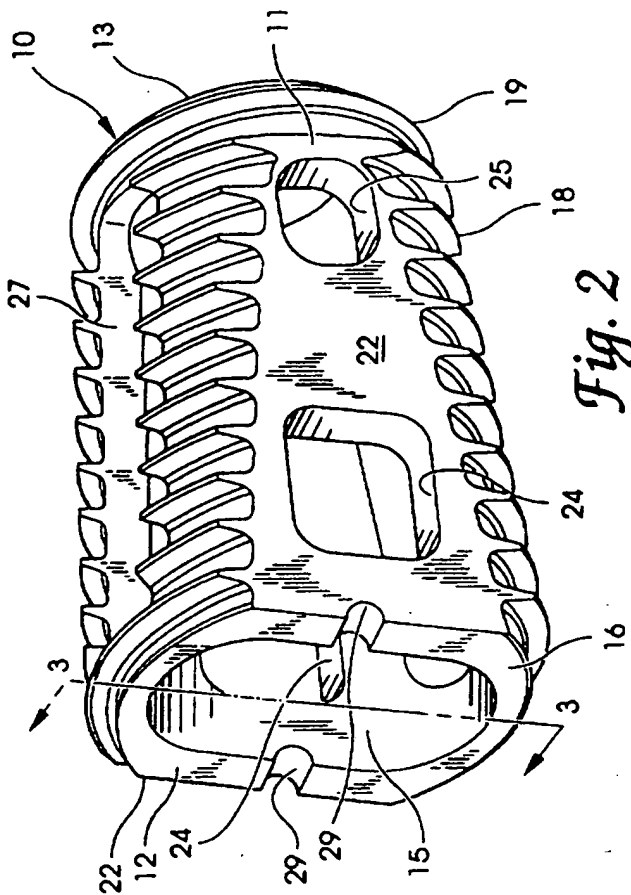


Fig. 2

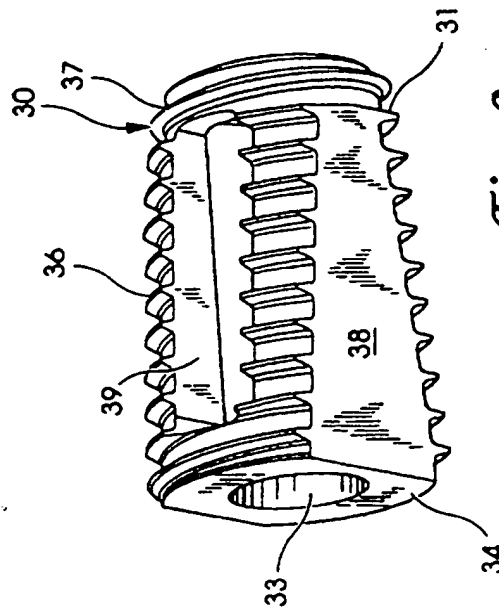


Fig. 8

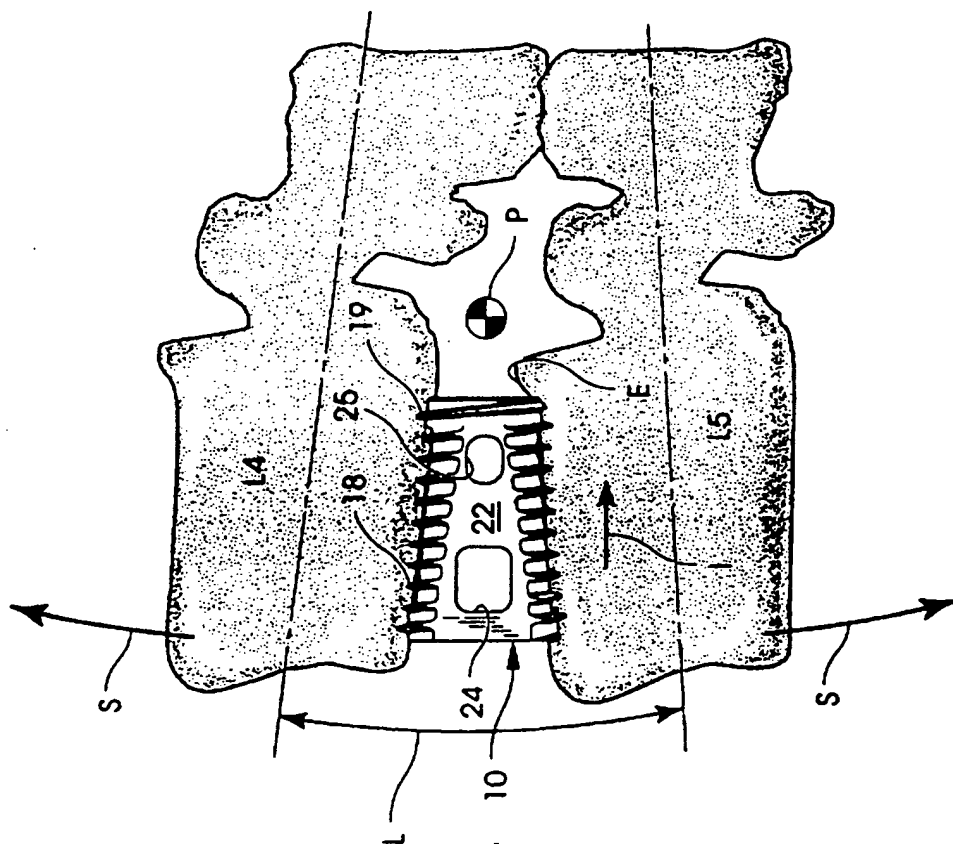


Fig. 7

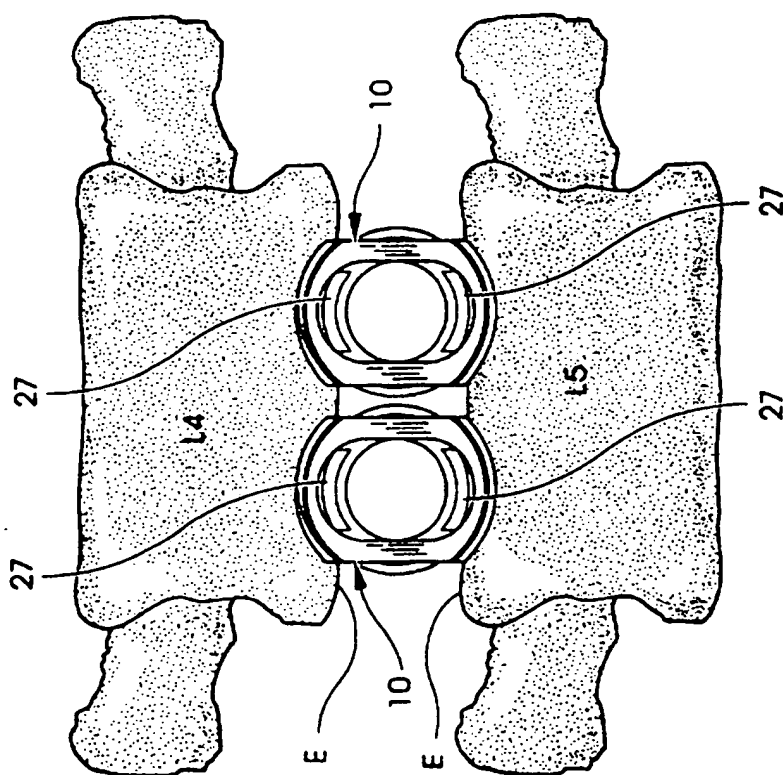
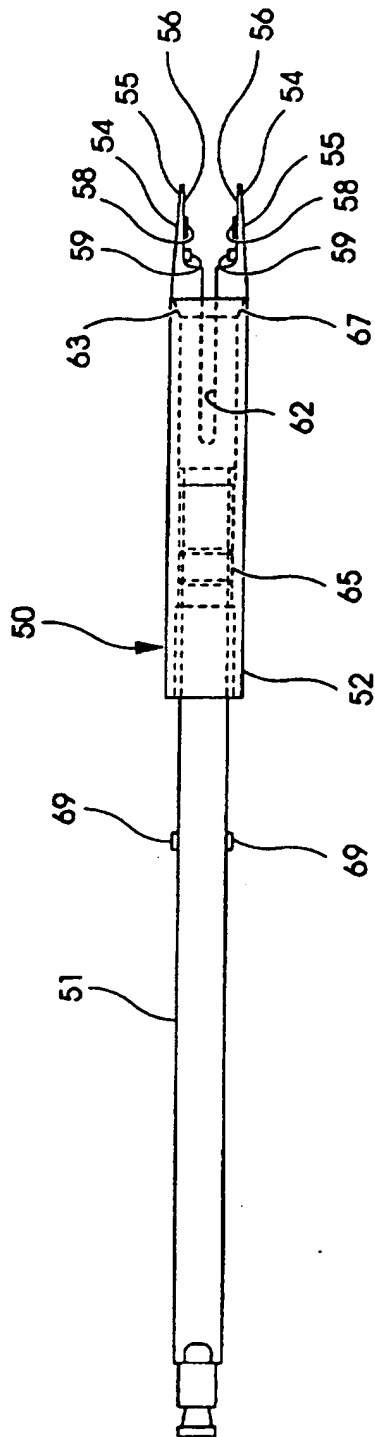
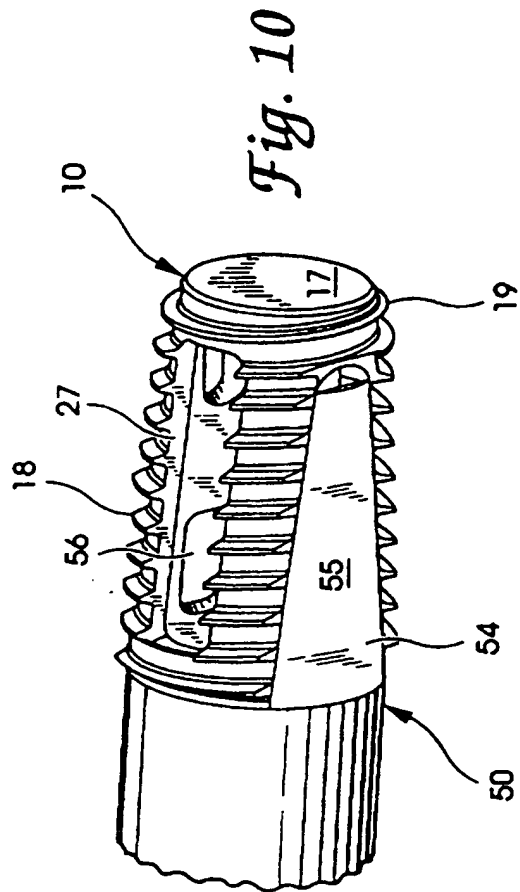


Fig. 6



*Fig. 9*



*Fig. 10*



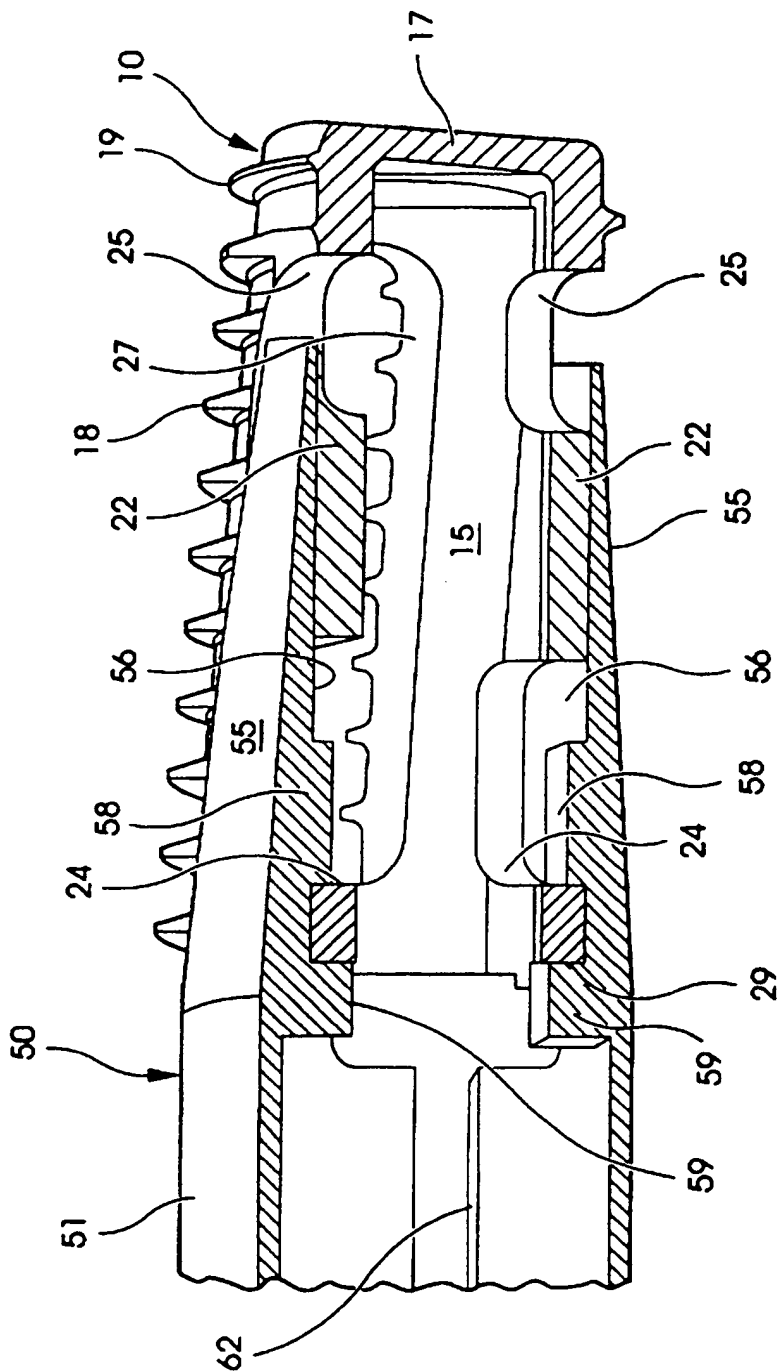


Fig. 11

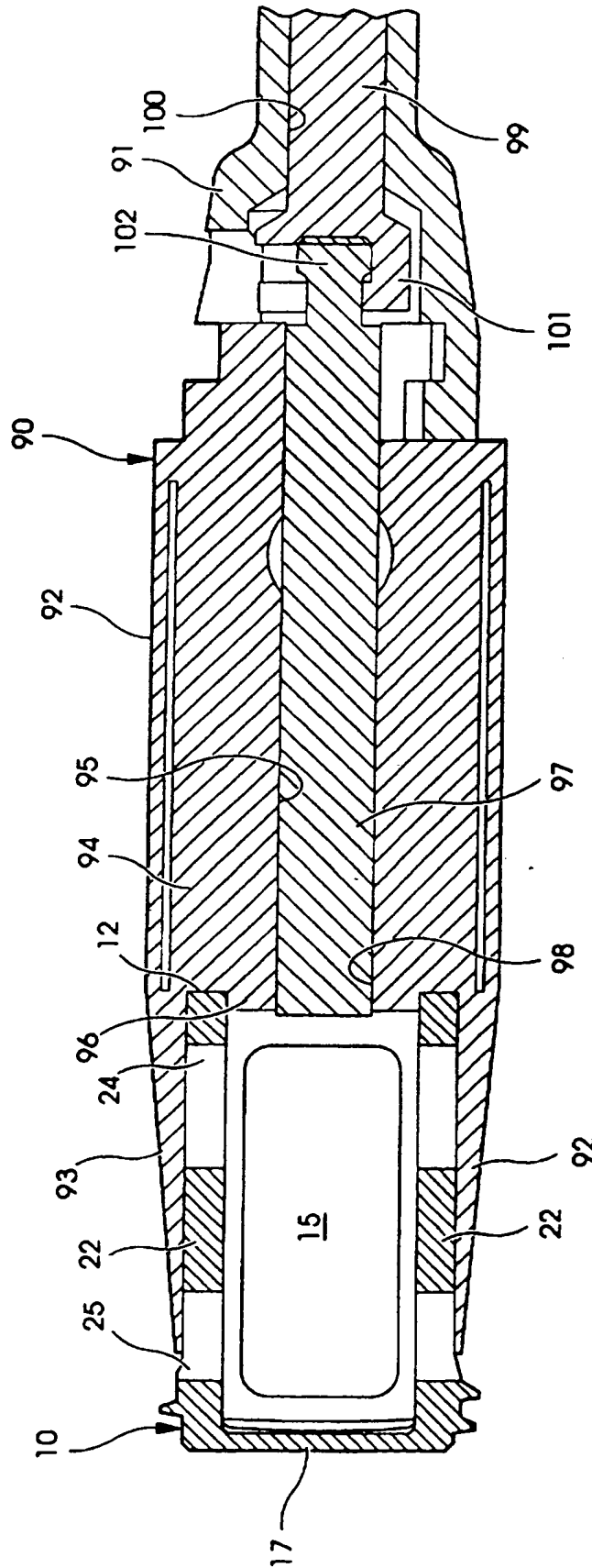
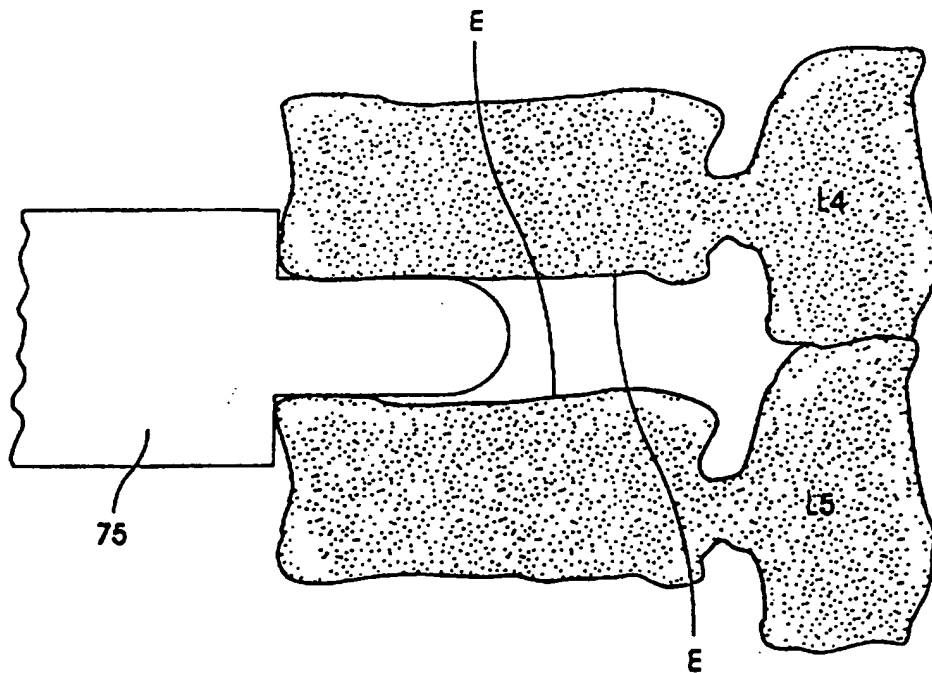
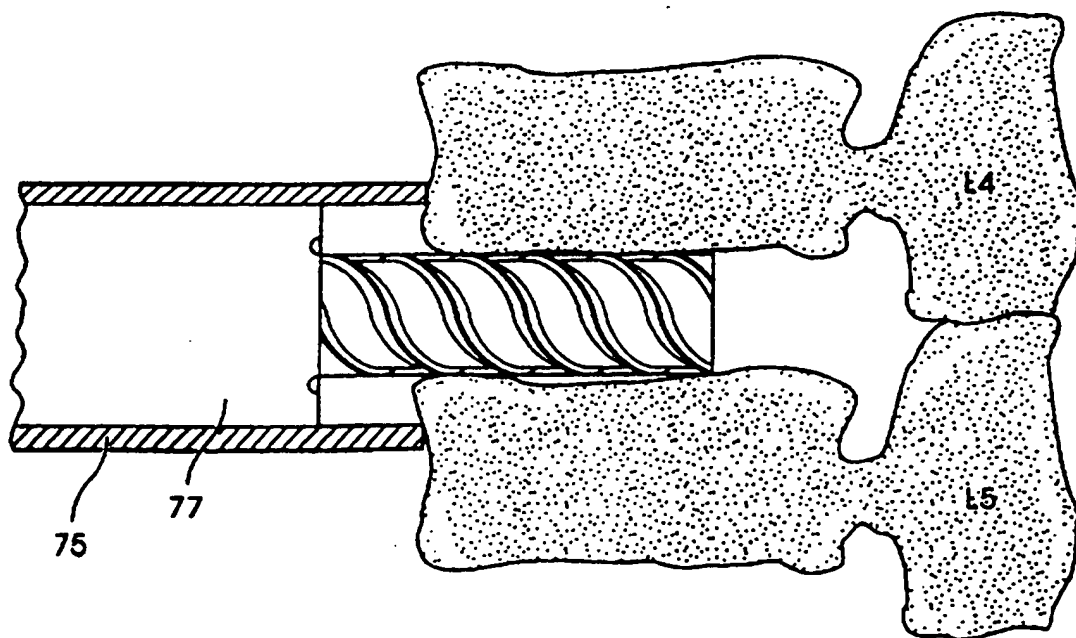


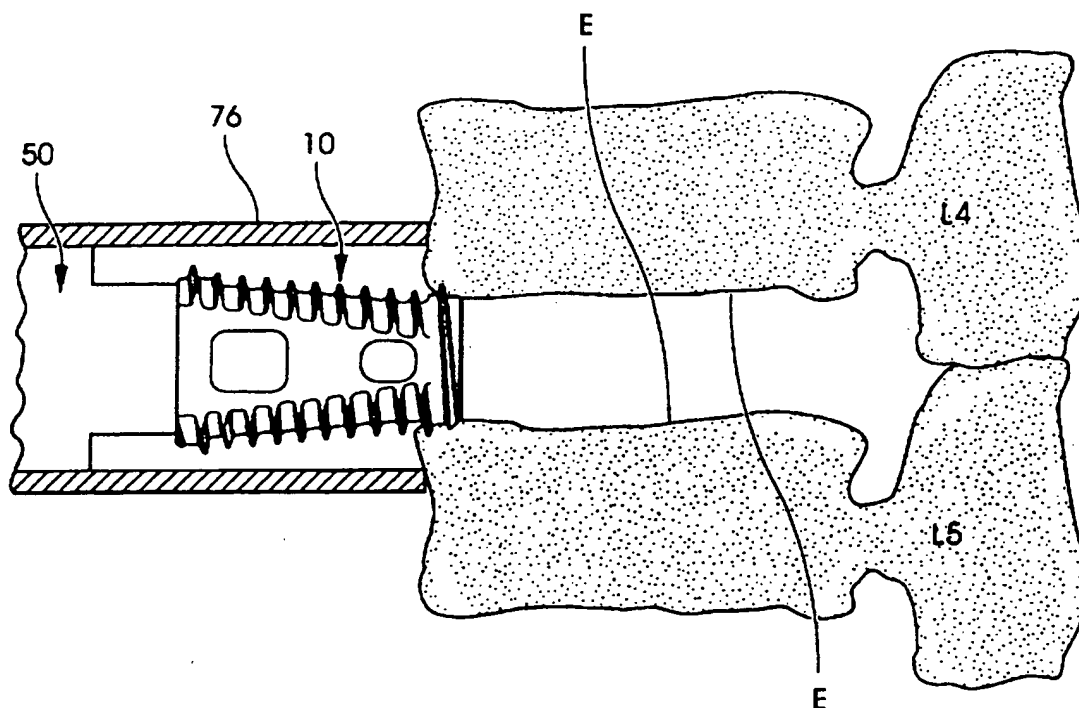
Fig. 12



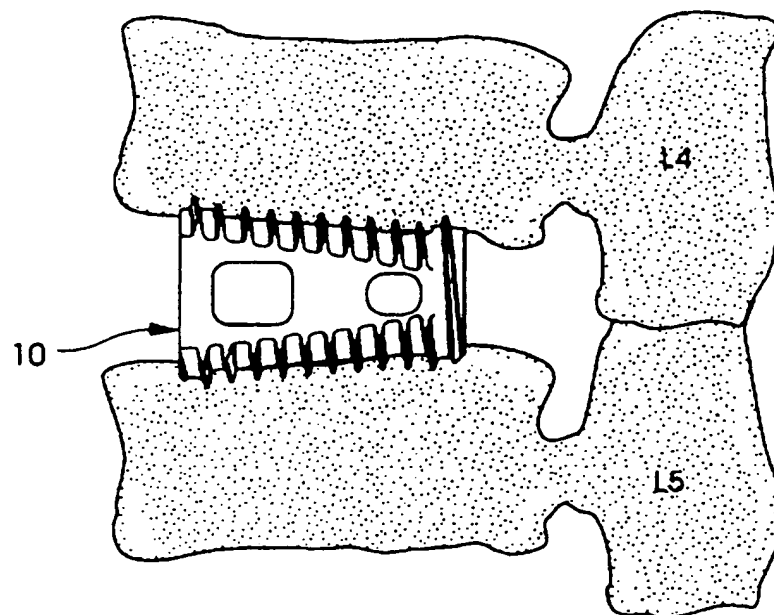
*Fig. 13(a)*



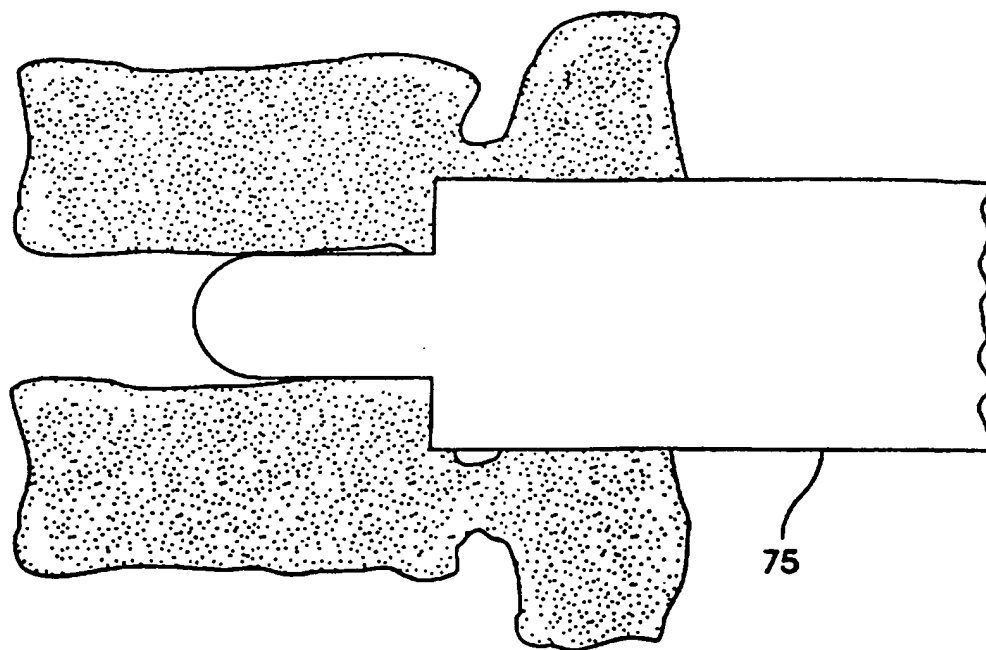
*Fig. 13(b)*



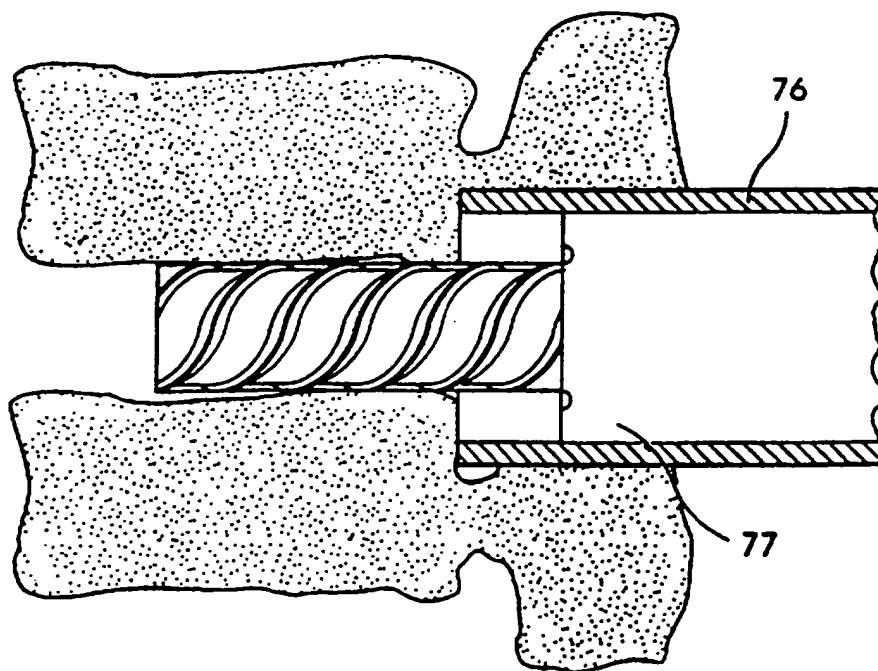
*Fig. 13(c)*



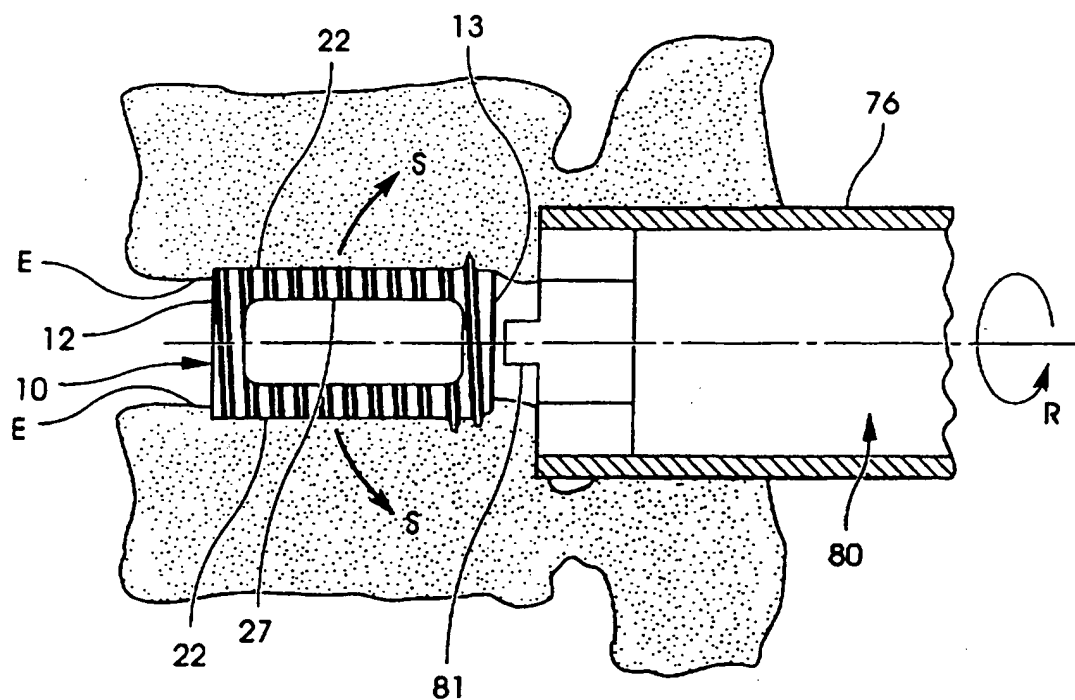
*Fig. 13(d)*



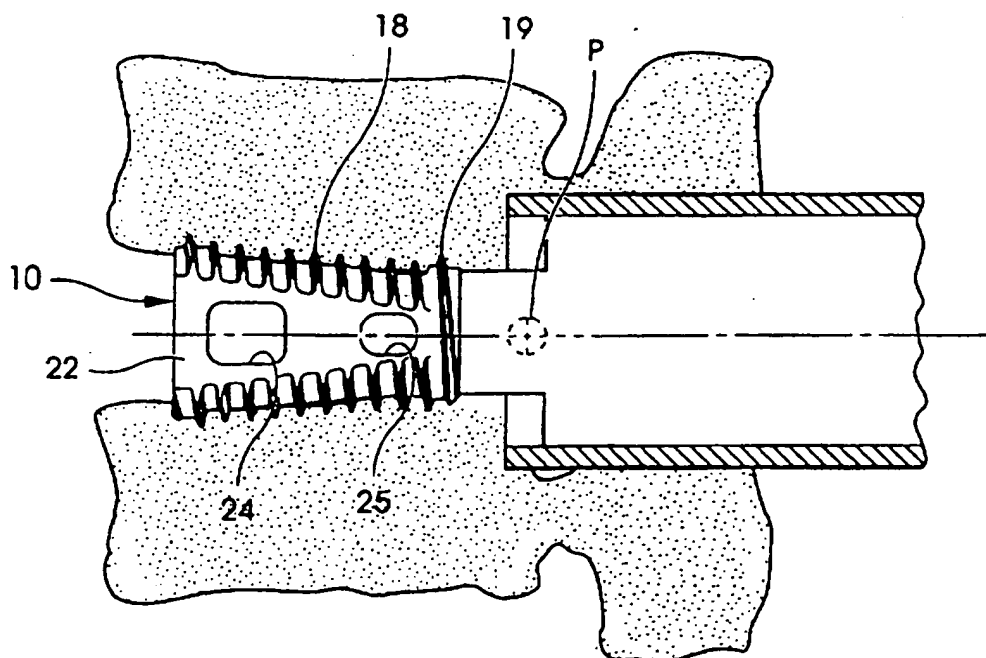
*Fig. 14(a)*



*Fig. 14(b)*



*Fig. 14(c)*



*Fig. 14(d)*

## INTERBODY FUSION DEVICE AND METHOD FOR RESTORATION OF NORMAL SPINAL ANATOMY

### BACKGROUND OF THE INVENTION

The present invention relates to an artificial implant to be placed into the intervertebral space left after the removal of a damaged spinal disc. Specifically, the invention concerns an implant that facilitates arthrodesis or fusion between adjacent vertebrae while also maintaining or restoring the normal spinal anatomy at the particular vertebral level.

The number of spinal surgeries to correct the causes of low back pain has steadily increased over the last several years. Most often, low back pain originates from damage or defects in the spinal disc between adjacent vertebrae. The disc can be herniated or can be suffering from a variety of degenerative conditions, so that in either case the anatomical function of the spinal disc is disrupted. The most prevalent surgical treatment for these types of conditions has been to fuse the two vertebrae surrounding the affected disc. In most cases, the entire disc will be removed, except for the annulus, by way of a discectomy procedure. Since the damaged disc material has been removed, something must be positioned within the intra-discal space, otherwise the space may collapse resulting in damage to the nerves extending along the spinal column.

In order to prevent this disc space collapse, the intra-discal space is filled with bone or a bone substitute in order to fuse the two adjacent vertebrae together. In early techniques, bone material was simply disposed between the adjacent vertebrae, typically at the posterior aspect of the vertebrae, and the spinal column was stabilized by way of a plate or a rod spanning the affected vertebrae. With this technique once fusion occurred the hardware used to maintain the stability of the segment became superfluous. Moreover, the surgical procedures necessary to implant a rod or plate to stabilize the level during fusion were frequently lengthy and involved.

It was therefore determined that a more optimum solution to the stabilization of an excised disc space is to fuse the vertebrae between their respective end plates, most optimally without the need for anterior or posterior plating. There have been an extensive number of attempts to develop an acceptable intra-discal implant that could be used to replace a damaged disc and yet maintain the stability of the disc interspace between the adjacent vertebrae, at least until complete arthrodesis is achieved. These "interbody fusion devices" have taken many forms. For example, one of the more prevalent designs takes the form of a cylindrical implant. These types of implants are represented by the patents to Bagby, U.S. Pat. No. 4,501,269; Brantigan, U.S. Pat. No. 4,878,915; Ray, U.S. Pat. Nos. 4,961,740 and 5,055,104; and Michelson, U.S. Pat. No. 5,015,247. In these cylindrical implants, the exterior portion of the cylinder can be threaded to facilitate insertion of the interbody fusion device, as represented by the Ray, Brantigan and Michelson patents. In the alternative, some of the fusion implants are designed to be pounded into the intra-discal space and the vertebral end plates. These types of devices are represented by the patents to Brantigan, U.S. Pat. Nos. 4,743,256; 4,834,757 and 5,192,327.

In each of the above listed patents, the transverse cross section of the implant is constant throughout its length and is typically in the form of a right circular cylinder. Other implants have been developed for interbody fusion that do not have a constant cross section. For instance, the patent to

McKenna, U.S. Pat. No. 4,714,469 shows a hemispherical implant with elongated protuberances that project into the vertebral end plate. The patent to Kuntz, U.S. Pat. No. 4,714,469, shows a bullet shaped prosthesis configured to optimize a friction fit between the prosthesis and the adjacent vertebral bodies. Finally, the implant of Bagby, U.S. Pat. No. 4,936,848 is in the form of a sphere which is preferably positioned between the centruns of the adjacent vertebrae.

Interbody fusion devices can be generally divided into two basic categories, namely solid implants and implants that are designed to permit bone ingrowth. Solid implants are represented by U.S. Pat. Nos. 4,878,915; 4,743,256; 4,349,921 and 4,714,469. The remaining patents discussed above include some aspect that permits bone to grow across the implant. It has been found that devices that promote natural bone ingrowth achieve a more rapid and stable arthrodesis. The device depicted in the Michelson patent is representative of this type of hollow implant which is typically filled with autologous bone prior to insertion into the intra-discal space. This implant includes a plurality of circular apertures which communicate with the hollow interior of the implant, thereby providing a path for tissue growth between the vertebral end plates and the bone or bone substitute within the implant. In preparing the intra-discal space, the end plates are preferably reduced to bleeding bone to facilitate this tissue ingrowth. During fusion, the metal structure provided by the Michelson implant helps maintain the patency and stability of the motion segment to be fused. In addition, once arthrodesis occurs, the implant itself serves as a sort of anchor for the solid bony mass.

A number of difficulties still remain with the many interbody fusion devices currently available. While it is recognized that hollow implants that permit bone ingrowth into bone or bone substitute within the implant is an optimum technique for achieving fusion, most of the prior art devices have difficulty in achieving this fusion, at least without the aid of some additional stabilizing device, such as a rod or plate. Moreover, some of these devices are not structurally strong enough to support the heavy loads and bending moments applied at the most frequently fused vertebral levels, namely those in the lower lumbar spine.

There has been a need for providing a hollow interbody fusion device that optimizes the bone ingrowth capabilities but is still strong enough to support the spine segment until arthrodesis occurs. It has been found by the present inventors that openings for bone ingrowth play an important role in avoiding stress shielding of the autologous bone impacted within the implant. In other words, if the ingrowth openings are improperly sized or configured, the autologous bone will not endure the loading that is typically found to be necessary to ensure rapid and complete fusion. In this instance, the bone impacted within the implant may resorb or evolve into simply fibrous tissue, rather than a bony fusion mass, which leads to a generally unstable construction. On the other hand, the bone ingrowth openings must not be so extensive that the cage provides insufficient support to avoid subsidence into the adjacent vertebrae.

Another problem that is not addressed by the above prior devices concerns maintaining or restoring the normal anatomy of the fused spinal segment. Naturally, once the disc is removed, the normal lordotic or kyphotic curvature of the spine is eliminated. With the prior devices, the need to restore this curvature is neglected. For example, in one type of commercial device, the BAK device of SpineTech, as represented by the patent to Bagby, U.S. Pat. No. 4,501,269, the adjacent vertebral bodies are reamed with a cylindrical

reamer that fits the particular implant. In some cases, the normal curvature is established prior to reaming and then the implant inserted. This type of construct is illustrated in FIG. 1 which reveals the depth of penetration of the cylindrical implant into the generally healthy vertebrae adjacent the instrumented discal space. However, this over-reaming of the posterior portion is generally not well accepted because of the removal of load bearing bone of the vertebrae, and because it is typically difficult to ream through the posterior portion of the lower lumbar segment where the lordosis is greatest. In most cases using implants of this type, no effort is made to restore the lordotic curvature, so that the cylindrical implant is likely to cause a kyphotic deformity as the vertebra settles around the implant. This phenomenon can often lead to revision surgeries because the spine becomes imbalanced.

In view of these limitations of the prior devices, there remains a need for an interbody fusion device that can optimize bone ingrowth while still maintaining its strength and stability. There is further a need for such an implant that is capable of maintaining or restoring the normal spinal anatomy at the instrumented segment. This implant must be strong enough to support and withstand the heavy loads generated on the spine at the instrumented level, while remaining stable throughout the duration.

#### SUMMARY OF THE INVENTION

In response to the needs still left unresolved by the prior devices, the present invention contemplates a hollow threaded interbody fusion device configured to restore the normal angular relation between adjacent vertebrae. In particular, the device includes an elongated body, tapered along substantially its entire length, defining a hollow interior and having an outer diameter greater than the size of the space between the adjacent vertebrae. The body includes an outer surface with opposite tapered cylindrical portions and a pair of opposite flat tapered side surfaces between the cylindrical portions. Thus, at an end view, the fusion device gives the appearance of a cylindrical body in which the sides of the body have been truncated along a chord of the body's outer diameter. The cylindrical portions are threaded for controlled insertion and engagement into the end plates of the adjacent vertebrae.

In another aspect of the invention, the outer surface is tapered along its length at an angle corresponding, in one embodiment, to the normal lordotic angle of lower lumbar vertebrae. The outer surface is also provided with a number of vascularization openings defined in the flat side surfaces, and a pair of elongated opposite bone ingrowth slots defined in the cylindrical portions. The bone ingrowth slots have a transverse width that is preferably about half of the effective width of the cylindrical portions within which the slots are defined.

A driving tool is provided for inserting the fusion device within the intra-discal space. In one feature, the driving tool includes a shaft having a pair of opposite tapered tongs situated at one end. The tongs are connected to the shaft by way of a hinge slot that biases the tongs apart to receive a fusion device therebetween. The driving tool is further provided with a sleeve concentrically disposed about the shaft and configured to slide along the shaft and compress the hinge to push the tongs together to grip the fusion device. Alternatively, an internal expanding collet may be used to internally hold the fusion device securely during insertion.

In one aspect of the driving tool, the tapered tongs have an outer surface that takes on the form of the tapered

cylindrical portions of the fusion device. The tongs also have a flat inward facing surface to correspond to the flat side surfaces of the fusion device. Thus, when the tongs are compressed against the fusion device, the inward facing surfaces of the tongs contact the flat sides of the fusion device and the outer surface of the tongs complete the conical form of the fusion device to facilitate screw-in insertion. The inward facing surface of the tongs may also be provided with projections to engage openings in the fusion device to permit driving and rotation of the device within the intra-discal space.

In another aspect of the invention, methods are provided for implanting the fusion device between adjacent vertebrae. In one method, the approach is anterior and includes the steps of dilating the disc space and drilling the end plates of the adjacent vertebrae to the minor diameter of the fusion device threads. A sleeve is inserted to provide a working channel for the drilling step and the subsequent step of implanting the fusion device. The implant is engaged with the driving tool, inserted through the sleeve and threaded into the prepared bore. The depth of insertion of the tapered fusion device determines the amount of angular separation achieved for the adjacent vertebrae.

In another inventive method, the insertion site is prepared posteriorly, namely the disc space is dilated and a minor diameter hole is drilled into the vertebral end plates. A sleeve is also arranged to provide a working channel for the drilling and insertion steps. The fusion device is inserted into the drilled hole with the flat side walls facing the adjacent vertebra. The device is then rotated so that the external threads on the cylindrical portion cut into and engage the adjacent vertebrae. In addition, since the fusion device is tapered, the tapered outer surface of the device will angularly separate the adjacent vertebrae to restore the normal anatomic lordosis.

#### DESCRIPTION OF THE FIGURES

FIG. 1 is a side-elevational view in the sagittal plane of a fusion device of the prior art.

FIG. 2 is an enlarged perspective view of an interbody fusion device according to one embodiment of the present invention.

FIG. 3 is a side cross-sectional view of the interbody fusion device shown in FIG. 2, taken along line 3—3 as viewed in the direction of the arrows.

FIG. 4 is an end elevational view from the anterior end of the interbody fusion device shown in FIG. 2.

FIG. 5 is a top-elevational view of the interbody fusion device shown in FIG. 2.

FIG. 6 is an A-P lateral view from the anterior aspect of the spine showing two interbody fusion devices according to FIG. 2 implanted within the interbody space between L4 and L5.

FIG. 7 is a sagittal plane view of the interbody fusion device implanted between L4 and L5 shown in FIG. 6.

FIG. 8 is a perspective view of an alternative embodiment of the interbody fusion device according to the present invention. FIG. 9 is a top-elevational view of an implant driver according to another aspect of the present invention.

FIG. 10 is an enlarged perspective view of the end of the implant driver engaged about an interbody fusion device, as depicted in FIG. 2.

FIG. 11 is an enlarged partial side cross-sectional view showing the implant driver engaging the interbody fusion device, as shown in FIG. 10.



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FIG. 12 is an enlarged partial side cross-sectional view showing an implant driver of an alternative embodiment adapted for engaging the interbody fusion device 10.

FIGS. 13(a)–12(d) show four steps of a method in accordance with one aspect of the invention for implanting the interbody fusion device, such as the device shown in FIG. 2.

FIGS. 14(a)–13(d) depict steps of an alternative method for implanting the interbody fusion device, such as the device shown in FIG. 2.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

An interbody fusion device 10 in accordance with one aspect of the present invention is shown in FIGS. 2–5. The device is formed by a solid conical body 11, that is preferably formed of a biocompatible or inert material. For example, the body 11 can be made of a medical grade stainless steel or titanium, or other suitable material having adequate strength characteristics set forth herein. The device may also be composed of a biocompatible porous material, such as porous tantalum provided by Implex Corp. For purposes of reference, the device 10 has an anterior end 12 and a posterior end 13, which correspond to the anatomic position of the device 10 when implanted in the intra-discal space. The conical body 11 defines a hollow interior 15 which is bounded by a body wall 16 and closed at the posterior end 13 by an end wall 17 (see FIG. 3). The hollow interior 15 of the device 10 is configured to receive autograft bone or a bone substitute material adapted to promote a solid fusion between adjacent vertebrae and across the intra-discal space.

In accordance with the invention, the interbody fusion device 10 is a threaded device configured to be screw threaded into the end plates of the adjacent vertebrae. In one embodiment of the invention, the conical body 11 defines a series of interrupted external threads 18 and a complete thread 19 at the leading end of the implant. The complete thread 19 serves as a "starter" thread for screwing the implant into the vertebral endplates at the intra-discal space. The threads 18 and 19 can take several forms known in the art for engagement into vertebral bone. For instance, the threads can have a triangular cross-section or a truncated triangular cross-section. Preferably, the threads have a height of 1.0 mm (0.039 in) in order to provide adequate purchase in the vertebral bone so that the fusion device 10 is not driven out of the intra-discal space by the high loads experienced by the spine. The thread pitch in certain specific embodiment can be 2.3 mm (0.091 in) or 3.0 mm (0.118 in), depending upon the vertebral level at which the device 10 is to be implanted and the amount of thread engagement necessary to hold the implant in position.

In one aspect of the invention, the conical body 11, and particularly the body wall 16, includes parallel truncated side walls 22, shown most clearly in FIG. 4. The side walls are preferably flat to facilitate insertion of the fusion device between the end plates of adjacent vertebrae and provide

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area between for bony fusion. The truncated side walls extend from the anterior end 12 of the device up to the complete threads 19 at the posterior end 13. Thus, with the truncated side walls 22, the device 10 gives the appearance at its end view of an incomplete circle in which the sides are cut across a chord of the circle. In one specific example, the interbody fusion device 10 has a diameter at its anterior end of 16.0 mm (0.630 in). In this specific embodiment, the truncated side walls 22 are formed along parallel chord lines approximately 12.0 mm (0.472 in) apart, so that the removed arc portion of the circle roughly subtends 90° at each side of the device. Other benefits and advantages provided by the truncated side walls 22 of the fusion device 10 will be described in more detail herein.

The conical body 11 of the device 10 includes a pair of vascularization openings 24 and 25 defined through each of the truncated side walls 22. These openings 24 and 25 are adapted to be oriented in a lateral direction or facing the sagittal plane when the fusion device is implanted within the intra-discal space. The openings are intended to provide a passageway for vascularization to occur between the bone implant material within the hollow interior 15 and the surrounding tissue. In addition, some bone ingrowth may also occur through these openings. The openings 24 and 25 have been sized to provide optimum passage for vascularization to occur, while still retaining a significant amount of structure in the conical body 11 to support the high axial loads passing across the intra-discal space between adjacent vertebrae.

The conical body 11 also defines opposite bone ingrowth slots 27, each of which are oriented at 90° to the truncated side walls 22. Preferably, these slots 27 are directly adjacent the vertebral end plates when the device 10 is implanted. More particularly, as the threads 18 and 19 of the device are screwed into the vertebral endplates, the vertebral bone will extend partially into the slots 27 to contact bone implant material contained within the hollow interior 15 of the device 10. As shown more clearly in FIG. 5, the bone ingrowth slots 27 are configured to provide maximum opening for bone ingrowth, in order to ensure complete arthrodesis and a solid fusion. Preferably, the slots have a lateral width that approximates the effective width of the threaded portions of the body. It has been found that the prior devices which utilize a plurality of small apertures do not promote a rapid and solid arthrodesis of the bone material. Instead, the smaller apertures often lead to pseudo-arthrosis and the generation of fibrous tissue. Since the bone ingrowth slots 27 of the present invention are directly facing the vertebrae, they are not situated in a portion of the device that must bear high loads. Instead, the truncated side walls 22 will bear most of the load passing between the vertebral end plates through the interrupted threads 18 and across the intra-discal space.

In a further feature, the anterior end 12 of the body wall 16 can define a pair of diametrically opposed notches 29, which are configured to engage an implant driver tool as described herein. Moreover, the end wall 17 at the posterior end 13 of the implant can be provided with a tool engagement feature (not shown). For example, a hex recess can be provided to accommodate a hex driver tool, as described further herein.

In one important feature of the interbody fusion device of the present invention, the body 11 includes a tapered or conical form. In other words, the outer diameter of the device at its anterior end 12 is larger than the outer diameter at the posterior end 13. As depicted in FIG. 3, the body wall 16 tapers at an angle A about the centerline CL of the device

10. The taper of the body wall 16 is adapted to restore the normal relative angle between adjacent vertebrae. For example, in the lumbar region, the angle A is adapted to restore the normal lordotic angle and curvature of the spine in that region. In one specific example, the angle A is 8.7940°. It is understood that the implant may have non-tapered portions, provided that the portions do not otherwise interfere with the function of the tapered body.

The taper angle A of the implant, coupled with the outer diameter at the anterior and posterior ends of the fusion device 10, define the amount of angular spreading that will occur between the adjacent vertebrae as the implant is placed or screwed into position. This feature is depicted more clearly in FIGS. 6 and 7 in which a preferred construct employing a pair of fusion devices 10 is shown. In the depicted construct, the devices 10 are disposed between the lower lumbar vertebrae L4 and L5, with the threads 18 and 19 threaded into the end plates E of the two vertebrae. As shown in FIG. 7, as the device 10 is threaded into the end plates E, it advances in the direction of the arrow I toward the pivot axis P of the vertebral level. The pivot axis P is nominally the center of relative rotation between the adjacent vertebrae of the motion segment. As the tapered fusion device 10 is driven further in the direction of the arrow I toward the pivot axis P, the adjacent vertebrae L4 and L5 are angularly spread in the direction of the arrows S. Depth of insertion of the fusion device 10 will determine the ultimate lordotic angle L achieved between the two vertebrae.

In specific embodiments of the implant 10, the outer diameter or thread crest diameter at the anterior end 12 can be 16, 18 or 20 mm, and the overall length of the device 26 mm. The sizing of the device is driven by the vertebral level into which the device is implanted and the amount of angle that must be developed.

In another aspect of the invention, device 10 is sized so that two such cylindrical bodies 11 can be implanted into a single disc space, as shown in FIG. 6. This permits the placement of additional bone graft material between and around the devices 10 in situ. This aspect further promotes fusion across the intra-discal space and also serves to more firmly anchor the devices between the adjacent vertebrae to prevent expulsion due to the high axial loads at the particular vertebral level.

In one specific embodiment of the interbody fusion device 10, the vascularization opening 24 is generally rectangular in shape having dimensions of 6.0 mm (0.236 in) by 7.0 mm (0.276 in). Similarly, the vascularization opening 25 is rectangular with dimensions of 4.0 mm (0.157 in) by 5.0 mm (0.197 in). Naturally, this opening is smaller because it is disposed at the smaller posterior end 13 of the device 10. The bone ingrowth slots 27 are also rectangular in shape with a long dimension of 20.0 mm (0.787 in) and a width of 6.0 mm (0.236 in). It has been found that these dimensions of the vascularization openings 24, 25 and slots 27 provide optimum bone ingrowth and vascularization. In addition, these openings are not so large that they compromise the structural integrity of the device or that they permit the bone graft material contained within the hollow interior 15 to be easily expelled during implantation.

As can be seen in FIG. 7, when the device is in position between the L4 and L5 vertebrae, the vascularization openings 24 and 25 are side facing to contact the highly vascularized tissue surrounding the vertebrae. In addition, as can be seen in FIG. 6, the bone ingrowth slots 27 are axially directed so that they contact the vertebral end plates E.

In an alternative embodiment of the invention, shown in FIG. 8, an interbody fusion device 30 is formed of a conical

body 31. The body wall 34 defines a hollow interior 33 as with the fusion device 10 of the previous embodiment. However, in this embodiment the truncated side wall 38 does not include any vascularization openings. Moreover, the bone ingrowth slots 39 on opposite sides of the device 30 are smaller. This means that the interrupted threads 36 on the exterior of the device 30 extend a greater length around the implant. Such a design could be utilized if a porous material (e.g., porous tantalum) were used to provide additional surface area for tissue ingrowth and anchorage to the adjacent bone. Also, this interbody fusion device 30 of the embodiment shown in FIG. 8 can have application at certain vertebral levels where the risk of expulsion of the device is greatest. Consequently, the amount of thread contact is increased to prevent such expulsion. Prior to insertion, the hollow interior 15 of the fusion device 10 is filled completely with bone or substitute to facilitate this pre-loading.

The interbody fusion device 10 can be implanted using an implant driver 50, shown in FIG. 9, according to one aspect of the invention. The implant driver 50 is comprised of a shaft 51 and sleeve 52 concentrically disposed about the shaft. Tongs 54 are formed at one end of the shaft for gripping the interbody fusion device 10 for implantation. The tongs include a tapered outer surface 55 and an opposite flat inner surface 56 adapted to engage the truncated side walls 22 of the interbody fusion device. The tapered outer surface 55 conforms to the root diameter of the interrupted threads 18 so that the tongs 54 essentially complete the full cylindrical shape of the body wall 16. The adaptation of the tong's tapered outer surface 55 facilitates screw insertion of the interbody fusion device 10 since the outer surface 55 will ride within the tapped bore in the vertebral endplates.

Each of the tongs is provided with interlocking fingers 58 and a driving projection 59 extending from the inner surface 56. The function of these components is shown more clearly with reference to FIG. 11. Referring first to FIG. 9, the shaft 51 defines a hinge slot 62 supporting each of the pair of tongs 54. The hinge slot 62 is configured so that the tongs will have a naturally biased position spread sufficiently apart to accept the tapered interbody fusion device 10 therebetween. The shaft 51 defines a conical taper 63 between the hinged slot 62 and each of the tongs 54. This conical taper mates with a conical chamfer 67 defined on the inner wall of the sleeve 52. Thus, as the sleeve 52 is advanced toward the tongs 54, the conical chamfer 67 rides against the conical taper 63 to close or compress the hinge slot 62. In this manner, the tongs 54 are pushed toward each other and pressed into gripping engagement with the interbody fusion device situated between the tongs.

The shaft 51 and sleeve 52 are provided with a threaded interface 65 which permits the sleeve 52 to be threaded up and down the length the shaft. Specifically, the threaded interface 65 includes external threads on the shaft 51 and internal threads on the sleeve 52 having the same pitch so that the sleeve can be readily moved up and down the implant driver 50. The shaft 51 is also provided with a pair of stops 69 which restrict the backward movement of the sleeve 52 to only the extent necessary to allow the tongs 54 to separate a sufficient distance to accept the interbody fusion device 10.

The use of the implant driver 50 is shown with reference to FIGS. 10 and 11. As can be seen in FIG. 10, the outer surface 55 of the tongs 54 reside generally flush with the root diameter of the interrupted threads 18. As seen in FIG. 11, the interlocking fingers 58 can be arranged to fit within the vascularization opening 24 on each of the truncated side walls 22. In a similar fashion, the driving projections 59

engage the driving tool slots 29 at the anterior end 12 of the conical body 11. The combination of the interlocking fingers 58 and driving projections 59 firmly engage the interbody fusion device 10 so that the device can be screw threaded into a tapped or untapped opening in the vertebral bone.

An alternative embodiment of the implant driver is shown in FIG. 12. The driver 90 includes a shaft 91, having a length sufficient to reach into the intradiscal space from outside the patient. Connected to the end of shaft 91 is a head which defines a pair of opposite tongs 93, each of which are configured for flush contact with the flat truncated side walls 22 of the fusion device 10. Like the tongs 54 of the previously described implant driver 50, the outer surface of the tongs is cylindrical to correspond to the cylindrical threaded portion of the device.

Unlike the implant driver 50, the driver 90 of the embodiment in FIG. 12 uses an expanding collet assembly to firmly grip the fusion device 10 for insertion into the body. Specifically, the head 92 defines a collet 94 having a central collet bore 95 formed therethrough. The collet 94 terminates in an annular flange 96 that at least initially has a diameter slightly smaller than the inner diameter of the fusion device 10 at its end 12. An expander shaft 97 slidably extends through the collet bore and includes a flared tip 98 situated adjacent and extending just beyond the annular flange 96. The flared tip 98 of the expander shaft 97 starts at a diameter sized to slide within the collet bore 95 and gradually flares to a diameter larger than the bore.

The implant driver 90 includes a puller shaft 99 slidably disposed within a bore 100 defined in the shaft 91. The puller shaft 99 has a locking chamber 101 at its end which engages a locking hub 102 formed at the end of the expander shaft 97. The puller shaft 99 projects beyond the end of shaft 91 for access by the surgeon. When the puller shaft 99 is pulled, it pulls the expander shaft 97 away from the annular flange 96 of the collet 94 so that the flared tip 98 becomes progressively engaged within the collet bore 95. As the tip 98 advances further into the bore 95, the annular flange 96 expands from its initial diameter to a larger second diameter sufficient for firm gripping contact with the interior of the fusion device 10. With the fusion device so engaged, the implant driver can be used to insert the device 10 into the surgical site, after which the expander shaft can be advanced beyond the collet bore to release the flared tip and, consequently, the fusion device.

In accordance with the present invention, two methods for implanting the interbody fusion device 10 are contemplated. First, with reference to FIGS. 12(a)-12(d), an anterior approach is shown. As a preliminary step, it is necessary to locate appropriate starting points for implanting the fusion device, preferably bilaterally. In the first step of the anterior approach, a dilator 75 is disposed between the vertebral end plates E to dilate the disc space between the L4 and L5 vertebrae. (It is understood, of course, that this procedure can be applied at other vertebral levels). In the second step, shown in FIG. 12(b), an outer sleeve 76 is disposed about the disc space. The outer sleeve 76 can be of a known design that is configured to positively engage the anterior aspect of the vertebral bodies to firmly, but temporarily, anchor the outer sleeve 76 in position. In essence, this outer sleeve 76 operates as a working channel for this laproscopic-type approach. In this step of FIG. 12(b), a drill 77 of known design is extended through the outer sleeve and used to drill out circular openings in the adjacent vertebral bodies. The openings can be tapped to facilitate screw insertion of the fusion device, although this step is not necessary.

In the next step shown in FIG. 12(c), the fusion device 10 is engaged by the implant driver 50 and extended through

the outer sleeve 76 until the starter thread 19 contacts the bone opening. The implant driver 50 can then be used to screw thread the fusion device into the tapped or untapped opening formed in the vertebral end plate E. It is understood that in this step, other suitable driving tools could be used, such as a screw driver type device to engage the driving tool slots 29 at the anterior end 12 of the device 10. As discussed previously, the degree of insertion of the fusion device 10 determines the amount of lordosis added or restored to the vertebral level. In the final step, the implant driver is removed leaving the fusion device 10 in position. It can be seen that once implanted, the closed end wall 17 is directed toward the posterior aspect of the vertebrae. The hollow interior 15 is open at its anterior end, but can be closed by a plastic or metal material, if necessary.

In a second inventive method, as depicted in FIGS. 13(a)-13(d), a posterior approach is implemented. The first two steps of the posterior approach are similar to that of the prior anterior approach, except that the dilator 75, outer sleeve 76 and drill 77 are introduced posteriorly into the instrumented region. This approach may require decortication and removal of vertebral bone to accept the outer sleeve 76. In the third step of this method, the fusion device 10 is inserted through the outer sleeve 76 into the dilated disc space. It is understood that the disc space is dilated only to the extent necessary to receive the implant with the truncated side walls 22 directly facing the vertebral end plates E. Thus, as shown in FIG. 13(c), the bone ingrowth slot 27 is facing laterally, rather than coronally, as expected for its final implanted position. A suitable driving tool 80 can be provided to project the fusion device 10 through the outer sleeve 76 and into the intra-discal space. In one embodiment, the driving tool 80 includes a projection 81 which is configured to engage a slot opening formed in the end wall 17 at the posterior end 13 of the fusion device 10. An internal thread (not shown) can be used to fix the device 10 to the driver 80.

Once the fusion device 10 has been advanced into the intra-discal space to the appropriate depth relative to the pivot axis P of the vertebrae, the driving tool 80 is used to rotate the implant in the direction of the rotational arrow R in FIG. 13(c). As the driving tool 80 is rotated, the device itself rotates so that the interrupted threads 18 start cutting into the vertebral bone at the end plates E. In this manner, the implant operates as a cam to separate the adjacent vertebrae in the direction of the spreading direction arrows S in FIG. 13(c). This camming approach provides a somewhat easier insertion procedure in that a single rotation is required to lock the implant into the vertebral bone. In contrast, the formerly discussed screw insertion technique requires continuous threading of the device into position.

With either technique, the position of the fusion device 10 with respect to the adjacent vertebrae can be verified by radiograph or other suitable techniques for establishing the angular relationship between the vertebrae. Alternatively, the preferred depth of insertion of the implant can be determined in advance and measured from outside the patient as the implant is positioned between the vertebrae.

It can be seen that the interbody fusion device 10, implant driver 50 and techniques of the present invention provide significant advantages over the prior devices and techniques. Specifically, the fusion device 10 provides a hollow threaded implant that maximizes the potential for bony fusion between adjacent vertebrae, while maintaining the integrity of the implant itself. It is understood that the spine endures significant loads along its axial length, which loads must be supported by the fusion device 10 at least until solid fusion

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is achieved. The device 10 also provides means for vascularization and tissue ingrowth to occur which speeds up the fusion rate and enhances the strength of the resulting fused bony mass. Another significant aspect is that the tapered shape of the implant allows the surgeon to restore and maintain the proper curvature or relative angle between vertebral bodies. This avoids the significant problems associated with prior devices in which product deformities arise and the spine goes out of balance. A further advantage achieved by the device and its implant driver is the capability for insertion either anteriorly or posteriorly using a laproscopic approach. Depending upon the vertebral level, either approach may be preferred, so it is important that the implant be adapted for insertion from either direction. Controlled insertion of the device is provided by the screw-in technique used for anterior insertion (vs. pounding in) and for the slide-in and cam method used for the posterior technique.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected. For example, while the device 10 has been disclosed for use in the spine, the structure and procedures of the present invention can also be used in other joint spaces, such as the ankle, wrist and subtalar joints. Moreover, while the device 10 of the preferred embodiment is shown tapered along its entire length, it is contemplated that a non-tapered or reverse tapered section can be added with the resulting device still falling within the scope of the invention.

What is claimed is:

1. A fusion device for facilitating arthrodesis in the disc space between adjacent vertebrae, comprising:

an elongated body having a length between a first end and a second end thereof, and a first diameter at said first end sized to be greater than the space between the adjacent vertebrae, said body further defining a hollow interior sized to receive bone growth promoting material therein;

said body having an outer surface with a pair of opposite cylindrical portions extending along substantially the entire length of said body and defining said first diameter, and a pair of substantially flat opposite side walls connected between said opposite cylindrical portions, said side walls extending along a substantial portion of said length of said body; and

external threads defined on said pair of opposite cylindrical portions of said outer surface and extending along substantially the entire length of said body.

2. The fusion device according to claim 1, wherein said cylindrical portions are tapered along a substantial portion of said length and define a second diameter at a second end thereof that is greater than said first diameter.

3. The fusion device of claim 1, further comprising a number of openings defined in said opposite side walls for communicating with said hollow interior.

4. The fusion device of claim 3, further comprising a pair of diametrically opposed slots defined through said threads

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in said cylindrical portion and communicating with said hollow interior, said opposed slots being elongated along said length of said body and each being larger than the combination of said number of openings.

5. The fusion device of claim 1, further comprising a pair of diametrically opposed slots defined through said threads in said cylindrical portion and communicating with said hollow interior, said opposed slots being elongated along said length of said body.

6. The fusion device of claim 5, wherein said opposed slots are rectangular in configuration and have a width dimension transverse to said length of said body; and

said cylindrical portions define an effective width between said opposite side walls and said opposed slots,

wherein said width dimension of said opposed slots is greater than said effective width of said cylindrical portions.

7. The fusion device of claim 1, wherein:

said flat side walls terminate near said first end; and said cylindrical portions and said threads are interrupted by said side walls and are circumferentially continuous thereafter from said side walls to said first end.

8. The fusion device of claim 1, wherein said body is closed at said first end and is open to said hollow interior at a second end opposite said first end.

9. The fusion device of claim 1, wherein said body includes a second end opposite said first end, said second end being open to said hollow interior.

10. The fusion device of claim 7, wherein:

said body includes a second end opposite said first end; and

said flat side walls terminate at said second end.

11. The fusion device of claim 10, wherein said opposite side walls each define a notch at said second end configured to receive a driving tool for implanting said device.

12. A fusion device for facilitating arthrodesis in the disc space between adjacent vertebrae, comprising:

an elongated body having a length, a first diameter at a first end and a larger second diameter at a second end opposite said first end, said first and second diameters sized to be greater than the space between the adjacent vertebrae, said body further defining a hollow interior sized to receive bone growth promoting material therein;

said body having an outer surface that is substantially continuously tapered from said first end to said second end with external threads defined on said outer surface and extending substantially entirely along said length of said body.

13. The fusion device of claim 12, further comprising a pair of diametrically opposed slots defined through said threads in said outer surface and communicating with said hollow interior, said opposed slots being elongated along said length of said body.

14. The fusion device of claim 12, wherein said body is closed at said first end and is open to said hollow interior at said second end.

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## MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 11, "STAT" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 11, "STAT" below. **TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(h).**

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. **THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.**

ITEM NBR	PATENT NUMBER	FEE CDE	FEE AMT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY SML YR ENT	STAT
1	5,782,919	183	880		08/411,017	07/21/98	03/27/95	04 NO	PAID

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Thomas Zdeblick, M. D. et al.	)	
	)	D. Isabella
Serial No. 08/411,017	)	
	)	Group Art Unit 3308
Filed March 27, 1995	)	
	)	March 28, 1997
INTERBODY FUSION DEVICE	)	
AND METHOD FOR	)	
RESTORATION OF NORMAL	)	
SPINAL ANATOMY	)	

TERMINAL DISCLAIMER IN APPLICATION

Assistant Commissioner for Patents  
Washington, D. C. 20231

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Sir:

I, Michael D. Beck, patent counsel for Danek Medical, Inc., a Tennessee corporation with a principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132, Shelby County, represent and certify that it is the assignee of record of the entire right, title and interest in patent application serial no. 08/411,017, filed on the 27<sup>th</sup> day of March, 1995 for INTERBODY FUSION DEVICE AND METHOD FOR RESTORATION OF NORMAL SPINAL ANATOMY by way of an Assignment recorded with the U.S. Patent and Trademark Office on May 1, 1995, Reel 7468, Frame 0855 and of pending U. S. patent application serial no. 08/413,353, filed March 30, 1995, entitled INTERBODY FUSION DEVICE AND METHOD OF RESTORATION OF NORMAL SPINAL ANATOMY by way of an Assignment recorded on May 1, 1995, Reel 7464, Frame 0394, and that I am empowered to act on behalf of the assignee.

Assignee hereby disclaims the terminal part of any patent granted on application serial no. 08/411,017, which would extend beyond the expiration date of any patent granted on application serial no. 08/413,353, and hereby agrees that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to any said patent shall be the same as the legal title to any patent granted on serial no. 08/413,353, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantees, their successors or assigns.

The evidentiary documents by which the Assignee claims title have been reviewed and I hereby certify that, to the best of my knowledge and belief, title is in the Assignee seeking to take the action.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Enclosed is \$110.00 as payment of the fee for a disclaimer (37 CFR §1.20(d)).

DANEK MEDICAL, INC.

By: Michael D. Beck  
Michael D. Beck, Esq.  
Patent Counsel

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